

### REMARKS

Reconsideration of the restriction and election requirement in view of the following remarks is requested respectfully.

Claims 1 to 30 are pending. No claims have been amended, added or canceled.

#### Discussion of the Office Action

A restriction has been required to one of two groups of inventions, characterized as Groups I and II. Group I (Claims 1 to 15) is drawn to methods of treating or preventing pancreatitis comprising administering to a patient a stable analog of spermine or spermidine. Group II (Claims 16 to 30) is drawn to methods of inducing liver regeneration comprising administering to a patient a stable analog of spermine or spermidine.

It is asserted in the Office Action that Groups I and II are independent or patentably distinct. Applicants respectfully traverse this restriction requirement.

It is submitted respectfully that the restriction requirement is deficient on its face in that no showing has been made that the claims are directed to independent inventions, 35 U.S.C. §121 mandating that the inventions be both independent and distinct. It is clear that the claims are not directed to independent inventions because of the common relationship involving compounds which are stable analogs of spermine or spermidine. As taught in the present application, these stable analogs of spermine or spermidine are generally related as being polyamine compounds as represented, for example, by Formula I ([0041] to [0049]).

As represented in the restriction requirement, the present claims define methods for treating or preventing pancreatitis or for inducing liver regeneration. Applicants teach in the present application that, while not intending to be bound by any theory or theories of operation, it is believed that pancreatitis may result from depletion of polyamines *in vivo*, and that liver regeneration may depend on a critical *in vivo* concentration of polyamines ([0039] and [0040]).

The purpose of § 121 is to avoid a situation which requires that separate and diverse searches be conducted on claims directed to unrelated subject matter. That is not the situation here because the relationship among the claimed polyamine compounds, which are preferably stable analogs of spermine or spermidine, and the contemplated association of

polyamines with pancreatitis and liver regeneration, is such that a reasonable search for the pancreatitis methods of Group I would necessarily lead to disclosures, to the extent any exist, of liver regeneration methods of Group II. Thus, for the sake of efficiency, applicants submit respectfully that it is incumbent upon the Examiner to conduct a search of all of the claimed subject matter.

It is respectfully submitted that the requirement is also deficient because it does not explain how the claimed methods are distinct.

**Provisional Election Under 37 C.F.R. § 1.143**

In accordance with 37 C.F.R. § 1.143, applicants hereby provisionally elect for prosecution the subject matter of Group I (Claims 1 to 15), which is drawn to methods of treating or preventing pancreatitis comprising administering to a patient a stable analog of spermine or spermidine. Applicants further elect the stable analog of spermidine, 1-methylspermidine (*i.e.*,  $\text{H}_2\text{N}-\text{CH}(\text{CH}_3)-(\text{CH}_2)_2-\text{NH}(\text{CH}_2)_4-\text{NH}_2$ ). Claims 1 to 7 and 15 read on the elected compound.

It is applicants' understanding that this election is being made to aid the Examiner in conducting a search and examination of the claimed subject matter, and is not to be construed as limiting the scope of applicants' claims. It is applicants' understanding also that, if the elected subject matter is found to be allowable over the prior art, the search and examination will be expanded to cover other species, until they include the full scope of the generic claims.

Applicants hereby affirm the right to file one or more divisional applications directed to any of the non-elected subject matter.

**Miscellaneous**

Applicants note that their file is lacking initialed copies of Forms PTO-1449 (Modified), submitted to the Patent Office with the Information Disclosure Statement dated March 25, 2004. Applicants respectfully request that the Examiner indicate that the documents cited in this Information Disclosure Statement have been considered by initialing the PTO-1449 form at the indicated locations, and that applicants be provided with copies of

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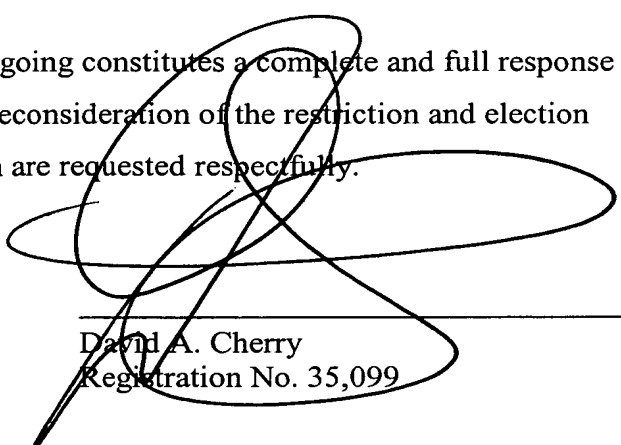
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the initialed form for their records. For the Examiner's convenience, copies of the Information Disclosure Statement and the associated PTO-1449 form are enclosed.

**Conclusion**

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, reconsideration of the restriction and election requirement and an early and favorable Action are requested respectfully.

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